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(54) Title: HYDROCOLLOID DELIVERY SYSTEM

(57) Abstract

A chewable delivery system stable in acidic, neutral or alkaline systems and having good mouthfeel is disclosed.

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HYDROCOLLOID DELIVERY SYSTEM

Field of the Invention

This invention relates to a delivery system for pharmacologically active materials. More particularly, this invention relates to a chewable delivery system which has good mouthfeel and which is capable of being utilized in an acidic, neutral or alkaline system.

Background of the Invention

When medication is prescribed and needs to be taken orally at regular intervals, the medication many times is distasteful, for example, cholestyramine. The distasteful nature of the medication often leads to failure of the patient to take the medication in the recommended dosages and at the scheduled intervals.

In order to overcome the reluctance of the patient to take the medication in the prescribed dosages and at the scheduled intervals, numerous delivery systems have been devised to make the taking of the medication more palatable to the patient.

One such delivery system is disclosed in US Patent 4,950,689. The '689 patent discloses a delivery system made from a pectin gel and an ingestible insoluble solid added to the pectin gel product in order to provide sufficient internal matrix strength to the gel. Further, the '689 patent teaches that the pectin gel, with the insoluble addition, can only be used in acidic pH so that the pH will be within the gelling range of the pectin to provide adequate gellation.

US Patent 4,695,463 is directed to a delivery system for active ingredients which comprises an insolubilized active ingredient and a crosslinked alginate or carrageenenate matrix which entraps an insolubilized active ingredient. The '463 patent teaches that a monovalent carrageenenate or alginate is dissolved in water with the active material and that the monovalent metal cations are then displaced

by multivalent cations, i.e., calcium to form a crosslinked matrix which will then precipitate. The precipitate is then recovered and dried to form the delivery system.

European Patent Publication 0 075 443 is directed to a delivery system for an antacid which is a chewable composition and which is prepared from a light textured frappe.

Canadian Patent Application 2044043 is directed to a delivery system for a drug and other materials, wherein the delivery system is in the form of a film and which may contain various gelling agents.

None of the aforedescribed references teach or suggest a chewable delivery system for a pharmacologically active material, which delivery system is a low moisture hydrocolloid containing system. Further, none of the references teaches a delivery system which provides a smooth creamy method of delivering pharmacological ingredients which otherwise have an unpleasant taste or texture so that an otherwise unpleasant pharmacological active material is ingested by the patient at the scheduled intervals in the prescribed dosage.

Summary of the Invention

Broadly, this invention contemplates a chewable delivery system for a pharmacologically active material comprising sweetener, a hydrocolloid and water, said delivery system comprising from about 50% to about 83% of solids.

Unless indicated otherwise, all percentages given herein are percentages by weight based on the weight of the entire composition.

Detailed Description

The term pharmacological, as used in the specification and claims means a material useful to treat a medical condition or having nutritive value.

A delivery system for a pharmacologically active material would be prepared by heating deonized water with stirring and adding a hydrocolloid such as carrageenan to the hot water and dissolving it therein. After the hydrocolloid is fully dissolved, sucrose is added to the aqueous solution which is stirred and heated until the sucrose is fully dissolved. A second syrup solution is prepared by placing corn syrup and water in a stainless steel beaker, with overhead stirring, and heating it in a boiling water bath. Thereafter, sucrose is added to the second solution with stirring until the sucrose dissolves completely. A portion of the carrageenan-containing solution is then added to the second solution with stirring until the mixture is uniform. Thereafter, a pharmacologically active material such as calcium carbonate is added and mixing is continued until it is uniformly dispersed. The beaker which contains the calcium carbonate is then heated to evaporate water until a predetermined weight is achieved. Thereafter, artificial flavoring may be added and the mixture may then be poured into suitable molds. The mold is then allowed to cool and the contents solidify. After cooling, the resultant gel is then ready to be ingested without the gritty chalky texture of the pharmacological component (calcium carbonate).

In preparing the chewable delivery system of this invention, it is important that the solids content of the delivery system be from about 50% to about 83%. In a preferred embodiment, the solids content of the system should be from about 78% to about 83%. When the solids content is between about 78% to about 83%, then a preservative may not be necessary for the composition because the delivery system may be stored without supporting microbial growth thereon.

When the solids content of the delivery system is between about 50% to up to about 78%, it is desirable to include an anionic or neutral preservative such as sodium benzoate, potassium sorbate, or a paraben in an amount of from about 0.02% to about 0.5%.

When preparing the delivery system, the amount of solids present is calculated and any excess water is removed in any satisfactory manner such as by boiling. When removing the excess water, attention should be given to the pharmacologically active material which is included in the delivery system. For example, acetaminophen may be partially or completely decomposed by heat and moisture. Therefore, care should be taken to incorporate such pharmacologically active materials into the molten formulation as rapidly and as late as possible to enable the delivery system to be useful for the heat sensitive active ingredients.

When carrageenan is used as the hydrocolloid, the carrageenan which is used is sulfated to the extent of about 18% to about 35% based on the weight of the molecule.

The amount of hydrocolloid, such as carrageenan, which is used may vary widely from about 2% to about 5.5%. Although an amount in excess of 5.5% may be used, there is no advantage to using such a large amount.

The delivery system may also include one or more additional hydrocolloids in a total amount of from about 0.5% to about 2%. Any suitable additional hydrocolloid which is compatible with the delivery system and the pharmacologically active material which is incorporated and which is stable at the pH ranges set forth herein may be used. Among such additional hydrocolloids may be mentioned locust bean gum, a polysaccharide sulfated to an extent greater than 35% based on the weight of the molecule, konjac mannan, a starch, guar gum and the like.

The pH of this delivery system may vary widely from about 2 to about 11. The fact that the pH of the delivery system may vary as widely as set forth, renders the delivery system useable with a wider range of pharmacologically active materials than other delivery systems. Any suitable sweetener may be used in the delivery system. The sweetener used in the delivery system of this invention may

be a natural sweetener, such as sucrose, fructose, xylose, ribose, glucose, mannose, galactose, corn syrup, and mixtures thereof and the like.

If desired, an artificial sweetener may also be used such as saccharin salts, aspartame, cyclamate salts, dipeptide based sweeteners, talen, dihydrochalcone, hydrogenated starch hydrolysate, sugar alcohols, and the like and mixtures thereof.

The amount of sweetener used will vary widely and is determined by what is calculated to be the desired solids content of the final composition. Thus, one need only calculate the amount of the solids being added to the water and the amount of water which must be removed to give the desired solids content.

If desired, a flavoring agent and a coloring agent may also be incorporated in the delivery system and may be selected from any of those deemed suitable for use in food and drug applications providing they are compatible with the remainder of the delivery system. The amount of flavoring agent used may be chosen from representative flavoring agents such as spearmint oil, cinnamon oil, oil of wintergreen, peppermint oils, fruit flavors such as citrus oil including lemon, orange, grape, lime and grapefruit and fruit essences including apple, strawberry, cherry, pineapple and the like. In addition, powdered flavorings may also be used.

The amount of flavoring agent employed is generally a matter of preference. However, a flavoring agent may be present in an amount of from about 0.05% to about 3%.

If a colorant is used, a pigment, such as titanium dioxide, may be used in an amount of up to about 1% and preferably up to about 0.6%. Any suitable colorant may be used.

The delivery system of this invention may be used to deliver a wide variety of pharmacological materials such as antacids and many other useful drugs.

Examples of useful pharmacologically active materials include: mineral supplements, analgesics, antipyretics, ion exchange resins, appetite suppressants, vitamins, anti-inflammatory substances, coronary dilators, cerebral dilators, peripheral vasodilators, anti-infectives, psychotropics, antimanics, stimulants, antihistamines, laxatives, decongestants, gastro-intestinal sedatives, antidiarrheal preparations, anti-anginal drugs, vasodilators, antiarrythmics, anti-hypertensive drugs, vasoconstrictors and migrane treatments, antibiotics, tranquilizers, antipsychotics, antitumor drugs, anticoagulants and antithrombotic drugs, hypnotics, sedatives, antiemetics, anti-nauseants, anticonvulsants, neuromuscular drugs, hyper- and hypoglycemic agents, thyroid and antithyroid preparations, diuretics, antispasmodics, uterine relaxants, mineral and nutritional additives, antiobesity drugs, anabolic drugs, erythropoietic drugs, antiasthmatics, expectorants, cough suppressants, mucolytics, anti-uricemic drugs and mixtures thereof.

In order to more fully illustrate the nature of this invention and the manner of practicing the same, the following examples are presented.

Example 1

Chewable Calcium Carbonate Antacid Carrageenan-based Confection

Deionized water (460 grams) was placed in a 2 liter, stainless steel beaker that was heated by a boiling water bath. The water was stirred with an overhead stirrer, and 19.85 grams of carrageenan (Gelcarin® GP-911, FMC Corporation, Philadelphia, PA 19103) was dissolved in the hot water. When the carrageenan was fully dissolved, 20.15 grams of sucrose was added to the aqueous solution. Stirring and heating continued until the sucrose was fully dissolved. Simultaneously, a syrup solution was prepared by placing 409.6 grams of corn syrup (42/43 DE, 80% solids by weight) and 54.4 grams of water in a 2 liter stainless steel beaker that was stirred with an overhead stirrer and heated in the boiling water bath. Next, 255.7 grams of sucrose was added to the beaker and stirring was continued until the sucrose had dissolved completely. A portion (280.3

grams) of the aqueous carrageenan solution was added to the syrup solution. After the mixture had become uniform, 100 grams of calcium carbonate (USP/NF) was added to it, and mixing was continued until it was uniformly dispersed. The beaker was transferred to a hot plate and heated to evaporate water until a predetermined weight of 842.362 grams was achieved. A solution of 2.5 grams of artificial wintergreen flavor (59.483, Firmenich, Inc.) dissolved in 20 grams of water was added and mixed thoroughly after which the mixture was poured into tubular molds. The mixture that was poured into the molds comprised 79.5% solids by weight. The molds were made from copper tubing which was capped at one end. For filling, the mold was held in a vertical position with the capped end at the bottom. After a mold was filled with hot solution, it was allowed to cool, the contents solidifying as it cooled. By removing the cap from the closed end of the mold, it was possible to push the solid, gelled product from the mold. Immediately, the gelled product was rolled in powdered starch to overcome any residual stickiness. It was calculated that 4.431 grams of gelled product contained 500 mg of calcium carbonate. Portions of the product weighing approximately 4.4 grams were sliced from the cylinder of product and chewed. The gel had a soft, chewy, creamy texture with the flavor of wintergreen predominating. The inherent gritty, chalky texture of the calcium carbonate was completely eliminated by the gel, which caused no toothpacking or stickiness.

Example 2

Chewable Calcium Carbonate Antacid Carrageenan-based Confection with Lower Solids Content

The method of Example 1 was followed exactly except that the water was not evaporated to the same extent, the flavor was changed to punch flavor (586.323/AP, Firmenich, Inc.), and FD&C Red #40 food coloring (0.20 gram) was added to the formulation. The solids content of this mixture was 66.0%. The solidified gel was more brittle than the gel of Example 1, but the organoleptic properties of both gels were very similar. After a storage period, syneresis of water and bacterial growth in the gel occurred, indicating that the solids, i.e., sugar,

content was too low to prevent these undesirable occurrences. No preservative had been added to this formulation to prevent the microbial growth.

Example 3

Chewable Calcium Carbonate Antacid Carrageenan-based Confection with Increased Calcium Carbonate Content

The method of Example 1 was followed exactly except that 200 grams of calcium carbonate was incorporated into the formulation and butterscotch flavoring was added in place of wintergreen flavoring. Before pouring the mixture into the molds, it was determined that the solids content of this formulation was 82.2% by weight. Each 5.08 gram portion of this gel was calculated to contain 1000 mg of calcium carbonate. The organoleptic properties of this gel were similar to the product described in Example 1. After extended storage the product has shown no microbial growth and retains its desirable organoleptic properties.

Example 4

Chewable Aluminum Hydroxide/Magnesium Hydroxide Antacid Carrageenan-based Confection

The method of Example 1 was followed except that 90 grams of magnesium hydroxide and 100 grams of aluminum hydroxide replaced the calcium carbonate and lemon flavoring replaced the wintergreen flavoring. Before pouring this formulation into the molds, it was determined that the solids content was 82.2% by weight. The gel was reported to be more sticky and paste-like than that of Example 1. However, the gel had an easy bite and satisfactory flavor and mouthfeel. In addition, as the gel dissolved in the mouth, it left a feeling of fine sand remaining. A 5.02 gram portion of this gel was calculated to contain 450 mg of magnesium hydroxide and 500 mg of aluminum hydroxide.

Example 5

Chewable Acetaminophen Carrageenan-based Confection

The method of Example 1 was followed exactly except that ethyl cellulose-coated acetaminophen (108.7 grams) replaced the calcium carbonate. Before pouring this formulation into the molds, the solids content was determined to be 78.7% by weight. It was calculated that a 4.53 gram portion of the solidified gel contained 500 mg of acetaminophen. There were small white particles of acetaminophen uniformly suspended in the gel; however, the sample had a smooth bite, and the taste of acetaminophen as well as its grittiness were eliminated.

Example 6

Chewable Ferrous Fumarate Carrageenan-based Confection

The method of Example 1 was followed except that 30.4 grams of ferrous fumarate replaced the calcium carbonate and spearmint flavor replaced the wintergreen flavor. In addition, 0.2% by weight of sodium benzoate was added to the formulation as a preservative. Before pouring this formulation into the molds, the solids content was determined to be 78.3% by weight. It was calculated that a 4.06 gram portion of the solidified gel contained 49 milligrams of elemental iron. The formulation poured easily into the molds. The dark red gel was less sticky than previous experiments with iron supplements. When chewed, there was no toothpacking or sticking. Furthermore, there was no aftertaste of the iron that was detectable.

Example 7

Chewable Multi-mineral Carrageenan-based Confection

The method of example 1 was followed except that the following mineral mixture was added to the syrup solution: 11.02 grams of ferrous fumarate, 111.12 grams of dicalcium phosphate•$2H_2O$, dibasic, 33.18 grams of magnesium oxide, 0.5 gram of cupric oxide, 3.73 grams of zinc oxide (40 mesh), 1.37 grams of

manganese sulfate, 0.039 gram of potassium iodide. As in Example 6, spearmint flavor and 0.2% by weight of sodium benzoate were added to the formulation. The resulting product chewed easily without any toothpacking or stickiness. However, there was some grittiness resulting from the use of granular dicalcium phosphate and the 40 mesh zinc oxide. Replacement of the granular dicalcium phosphate with powdered material was shown to eliminate much of the grittiness, and replacement of the 40 mesh zinc oxide with powdered zinc oxide would eliminate the remaining grittiness, making the product completely satisfactory.

Example 8

Chewable Calcium Carbonate/Ferrous Fumarate Carrageenan-based Confection

The method of Example 1 was followed except that 300 grams of calcium carbonate and 11.02 grams of ferrous fumarate were added to the syrup solution, and spearmint flavor and 0.2% by weight of sodium benzoate were used. The ferrous fumarate was added first and fully dispersed before the calcium carbonate was added in three equal portions. Each addition of calcium carbonate was followed by sufficient mixing to completely disperse it before adding the next portion. Before pouring this formulation, the solids content was calculated to be 79.1%. When chewed, the product had a clean bite without any iron aftertaste or a chalky taste. Also, there was no perceptible toothpacking or stickiness with this product. A 5.806 gram portion of the gelled product contained 1500 mg of calcium carbonate and 18 mg of elemental iron.While this invention has been described in terms of certain preferred embodiments and illustrated by specific examples, the invention is not to be construed as limited except as set forth in the following claims.

Claims

1. A chewable composition for delivery of a pharmacologically active material to a user comprising sweetener carrageenan and water, said composition comprising from about 50% to about 83% of solids.

2. A chewable composition according to claim 1 wherein the hydrocolloid is carrageenan sulfated to the extent of from about 18% to about 35% based on the weight of the molecule.

3. A chewable composition according to claim 1 wherein the solids content of said composition comprises from about 78% to about 83% of solids and said chewable composition does not support microbial growth thereon.

4. A chewable composition according to claim 1 wherein said composition is stable at acid, neutral and alkaline conditions.

5. A chewable composition according to claim 1 wherein said composition is stable at a pH of from about 2 to a pH of about 11.

6. A chewable composition according to claim 1 wherein carrageenan is present in an amount from about 2% to about 5.5% and optionally one or more of an additional hydrocolloid is present in a total amount of from about 0.5% to about 2%.

7. A chewable composition according to claim 6 wherein the additional hydrocolloid is locust bean gum.

8. A chewable composition according to claim 6 wherein the additional hydrocolloid is a polysaccharide sulfated to an extent greater than 35% based on the weight of the molecule.

9. A chewable composition according to claim 6 wherein the additional hydrocolloid is konjac mannan.

10. A chewable composition according to claim 6 wherein the additional hydrocolloid is a starch.

11. A chewable composition according to claim 6 wherein the additional hydrocolloid is guar gum.

12. A chewable composition according to claim 1 comprising a pharmacologically active material.

13. A chewable composition according to claim 12 wherein the pharmacologically active material is an antacid.

14. A chewable composition according to claim 12 wherein the pharmacologically active material is an antihistamine material.

15. A chewable composition according to claim 12 wherein the pharmacologically active material is an anti-inflammatory material or antipyretic material.

16. A chewable composition according to claim 12 wherein the pharmacologically active material is a nutritional supplement.

17. A chewable composition according to claim 12 wherein the pharmacologically active material is an antibiotic or antiviral material.

18. A chewable composition according to claim 12 wherein the pharmacologically active material is an expectorant or anti-tussive material.

19. A chewable composition according to claim 1 wherein the sweetener comprises sucrose.

20. A chewable composition according to claim 1 wherein the sweetener comprises fructose.

21. A chewable composition according to claim 1 wherein the sweetener comprises galactose.

22. A chewable composition according to claim 1 wherein the sweetener is an artificial sweetener.

23. A chewable composition according to claim 22 wherein the sweetener is selected from group consisting of aspartame, saccharin or cyclamate and mixtures thereof.

24. A chewable composition according to claim 1 wherein an anionic or neutral preservative is present.

25. A chewable composition according to claim 24 wherein said preservative is present in an amount of from about 0.02% to about 0.5%.

26. A chewable composition according to claim 24 wherein said preservative is sodium benzoate, potassium sorbate, or a paraben.

27. A chewable composition according to claim 24 wherein said delivery system comprises from about 50% to up to about 78% of solids.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 379 147 A (STERLING DRUG INC) 25 July 1990 see page 4, line 1 - line 23	1-18
A	US 5 298 261 A (PEBLEY WALTER S ET AL) 29 March 1994 see column 4, line 7 - line 24 see column 19; example 81	1-18
A	DE 44 15 999 A (BOLDER ARZNEIMITTEL GMBH) 9 November 1995 see column 2, line 49 - column 3, line 45	1-18
A	GB 2 160 771 A (LION CORP) 2 January 1986 see page 3; example 4	1-18

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Date of the actual completion of the international search	Date of mailing of the international search report
3 July 1998	10/07/1998

Name and mailing address of the ISA	Authorized officer
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